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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JOHN S. PRATT
KILPATRICK STOCKTON LLP
1100 PEACHTREE
SUITE 2800
ATLANTA, GA 30309

EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/10/2003 24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/457,771	EMANUELE ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 July 2003* .

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-4,6-12 and 14-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-4,6-12 and 14-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

An amendment was received and entered as Paper No 23 on 7/18/03.

Claims 17-31 were added as requested.

Claims 1-4, 6-12, and 14-31 are pending and under consideration in this Office Action.

This Action contains new grounds of rejection and is NON-FINAL

Compliance with Sequence Rules

Applicant's submission of 7/18/03 was sufficient to place the Application in compliance with 37 CFR 1.821-1.825.

Rejections Withdrawn

The double patenting rejection is withdrawn in view of Applicant's arguments.

After further consideration, the enablement and written description rejections are withdrawn.

The previous rejections of claims 1-4, 6-12, and 14 under 35 USC 112, second paragraph are withdrawn in view of Applicant's amendments which necessitated new grounds of rejection.

Claim Objections

Claims 1-4, 6-12, and 14-31 are objected to because they recite molecular weights but fail to give any units, or to define molecular weight as relative molecular mass M_r. Insertion of the unit "Daltons" is suggested. These claims also recite a general structural formula for a poloxamer that contains subscripts 'a' and 'b', but these subscripts are never defined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-12, and 14-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-12, and 14-31 are indefinite because the intended scope of the nucleic acids intended to be embraced is unclear. Specifically, it is unclear if Applicant intends to claim composition comprising oligonucleotides such antisense , triplex formers, and ribozymes, or whether Applicant intends to claim nucleic acid sequences encoding such oligonucleotides, e.g. expression vectors encoding antisense oligonucleotides.

Similarly, claims 17, 20, and 28 are indefinite because it is unclear whether the recited nucleic acid sequence is required to encode an antisense oligonucleotide, or whether Applicant intends "antisense oligonucleotide" to be an alternative to a "nucleic acid sequence".

Claim 31 is indefinite because it recites "the animal" without antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 8-12, 16-20, and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Allison et al (US Patent 5,376,369, issued 12/27/94).

Allison taught that Pluronics L101, L121, and L122, could be used as an adjuvant in the delivery of whole viruses in vivo as vaccines (see abstract, and column 23, lines 24-55, especially, lines 30, 31, 34, 36, 38, 46, and 55). Note that L101 and L122 are the trade names for CRL 8131 and CRL 8142, respectively (see e.g. Table II at page 17 of instant specification).

Whole viruses comprise nucleic acids encoding genes, and can be considered expression vectors. To the extent that the viruses must be propagated in order to make the disclosed vaccines, the nucleic acids are amplified. The limitation requiring an expression vector capable of expressing the genes is anticipated by the viruses themselves, which are clearly capable of expressing their own genes. The compositions can be considered to comprise an antimicrobial drug (claim 18) in the form of viral antigens. .Because the viruses comprise genes required for viral transcription, they comprise genes that are used for altering gene activity, particularly during the process of viral amplification

Thus Allison anticipates the claims.

Claims 8 and 16 were included in this rejection as a result of Applicant's amendment that effectively broadens the scope of the claims to include poloxamer compositions comprising any expression vector.

Claims 1-3, 8-11, 16-21, and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Wasmoen et al (US Patent 5,656,275, issued 8/12/97), as evidenced by Osorio et al (WO 99/39733, issued 8/12/99).

Wasmoen taught that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses in vivo (see column 3 line 66 to column 4, line 28). Whole viruses comprise nucleic acids encoding genes, and can be considered expression vectors. To the extent that the viruses must be propagated in order to make the disclosed vaccines, the nucleic acids are amplified. The limitation requiring an expression vector capable of expressing the genes is anticipated by the viruses themselves, which are clearly capable of expressing their own genes. The compositions can be considered to comprise an antimicrobial drug (claim 18) in the form of viral antigens. Because the viruses comprise genes required for viral transcription, they comprise genes that are used for altering gene activity, particularly during the process of viral amplification. The viruses are modified to express foreign antigens for the purpose of providing an immune response against the antigens. It is noted that Wasmoen exemplifies a virus in which the antigen is expressed and incorporated into the viral particle, prior to administration of the virus to a recipient animal. However, a review of the art indicates that the virus of Wasmoen should be capable of infecting cells in vivo and subsequently producing a foreign antigen in infected cells in vivo, thereby meeting the limitations of claims 21 and 29. See Osorio et al who teach recombinant raccoon poxviruses similar to those of

Wasmoen, containing foreign genes encoding antigens and immunomodulatory factors for expression in the recipient (page 6, line 22 to page 7, line 10, page 7, line 21 to page 8, line 7, page 10, lines 4-22.

Thus Wasmoen anticipates the claims.

Claims 8 and 16 were added to this rejection as a result of Applicant's amendment that effectively broadens the scope of the claims to include poloxamer compositions comprising any expression vector.

Claims 1, 8, 17, 18, and 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee (US Patent 5,470,568, issued 11/28/95).

Lee teaches a method of transfecting cells in vitro with plasmid DNA or antisense in a medium containing a poloxamer such as F68. . See e.g. abstract; column 3, lines 44-56; column 4, lines 3-9; column 10, line 40 to column 11, line15; Example 3 at columns 12 and 13; and claim 22. The poloxamer may have a molecular weight in the range of 2000-20000 D, a hydrophobic component of 950-4000 D, and a hydrophilic component constituting as little as 45% by weight. See column 7, lines 21-30. the treatment may occur either before, after, or during transfection. See e.g. claim 20.

Response to Arguments

Applicant's arguments filed 7/18/03 have been fully considered but are unpersuasive.

Applicant argues at page 17 of the response that neither Allison nor Wasmoen teach an isolated or amplified nucleic acid. This is unpersuasive because the specification does not define the terms "isolated" or "amplified", so they have been given their broadest reasonable interpretation. In this interpretation the nucleic acids can be

considered to be isolated because they are removed from cells in which the viruses were produced. The nucleic acids can also be considered to be amplified because the viruses themselves are amplified by the process of their synthesis.

Applicant also argues that neither Allison nor Wasmoen teach delivery into a cell as claimed in instant claim 25. This argument is unpersuasive because it is unsupported. Applicant has presented no evidence that the viruses of either Allison or Wasmoen fail to enter cells as would normally be expected in the delivery of live whole viruses. It is unclear how the compositions of Wasmoen and Allison could function if they did not enter cells. For these reasons the rejections are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 7, 9, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wasmoen et al (US Patent 5,656,275, issued 8/12/97) in view of Miyamura et al (US Patent 5,372,928, issued 12/13/94).

Wasmoen taught that Pluronic L121 could be used as an adjuvant in the delivery of whole virus vaccines in vivo (see column 3 line 66 to column 4, line 28). Whole viruses comprise nucleic acids encoding genes, and can be considered expression

vectors. To the extent that the viruses must be propagated in order to make the disclosed vaccines, the nucleic acids are amplified.

Wasmoen did not teach the addition a surfactant and an alcohol to the vaccine.

Miyamura teaches that vaccine compositions are often modified by the addition of ethanol and Tween 80. See e.g. column 19, lines 5-22. Arriving at the appropriate concentrations of these additives is considered to be routine optimization.

Thus the invention as a whole was prima facie obvious.

Claims 25, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torrence et al (US Patent 5,583,032, issued 12/10/96) in view of Lee (US Patent 5,470,568, issued 11/28/95).

Torrence teaches a method of cleaving a viral RNA in a cell in culture by delivering to the cell antisense against the virus. Torrence does not teach a composition comprising antisense and a non-ionic block copolymer.

Lee teaches a method of transfecting cells in vitro with plasmid DNA or antisense. See e.g. abstract; column 3, lines 44-56; column 4, lines 3-9; column 10, line 40 to column 11, line15; Example 3 at columns 12 and 13; and claim 22. The cells may be treated with a poloxamer with a molecular weight in the range of 2000-20000 D, having a hydrophobic component of 950-4000 D, and in which the hydrophilic component constitutes as little as 45% by weight. See column 7, lines 21-30.

Lee does not teach antisense targeted against an RNA message of a virus.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Torrence by including the nonionic block copolymer of Lee in the transfection composition, because Lee teaches that this will increase the efficiency of transfection. See e.g. claim 20.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

DAVE T. NGUYEN
PRIMARY EXAMINER

Richard Schnizer, Ph.D.